PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:	Confirmation No.: 4091
MOREIN et al.	Examiner: Ahmed, Hasan Syed
Appln. No.: 10/507,368	Art Unit: 1615
Filed: September 20, 2004	Attorney Dkt. No.: 026220-00054

For: NO-DONATING NSAIDS ABSORBED INTO CARRIER PARTICLES

RESPONSE TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENT

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

January 22, 2008

Sir:

This paper is filed in response to the Restriction and Election of Species Requirement dated November 21, 2007, in connection with the above-identified patent application. The period of response is extended one (1) month from December 21, 2007, to January 22, 2008, by a one (1) month Petition for Extension of Time and by the fact that January 21, 2008 falls on a Federal Holiday.

The Restriction and Election of Species Requirement asserted that the claims define twelve (12) allegedly independent and distinct inventions and required the Applicant to elect one of the following twelve inventions:

Group I, claims 1-9 and 19-25, drawn to a solid drug delivery composition comprising NO-donating NSAID(s) absorbed into porous particles.

Group II, claims 1, 10, and 12-18, drawn to a solid drug delivery composition comprising NO-donating NSAID(s) and surfactant(s) absorbed into porous particles.

Group III, claims 1 and 11, drawn to a solid drug delivery composition comprising a combination of NO-donating NSAID(s) with and without surfactant(s) absorbed into porous particles.

Group IV, claims 1, 26, and 27, drawn to a solid drug delivery composition comprising NO-donating NSAID(s) and surfactant(s) absorbed into porous particles mixed with enteric coated pellets comprising a H+, K+-ATPase inhibitor.

Group V, claims 1, 28, and 35-38, drawn to a process for producing porous particles comprising mixing the NO-donating NSAID(s) with porous particles.

Group VI, claims 1 and 29, drawn to a process for producing porous particles comprising dissolving the NO-donating NSAID(s) in alcohol.

Group VII, claims 1 and 30, drawn to a process for producing porous particles comprising melting the NO-donating NSAID(s).

Group VIII, claim 1 and 31, drawn to a process for producing porous particles comprising NO-donating NSAID(s) and surfactant(s) comprising mixing the NO-donating NSAID(s) and surfactant(s).

Group IX, claims 1 and 32, drawn to a process for producing porous particles comprising NO-donating NSAID(s) and surfactant(s) comprising melting the NO¬donating NSAID(s) and surfactant(s).

Group X, claims 1, 33, and 34, drawn to a process for producing porous particles comprising NO-donating NSAIDS(s) comprising mixing the NO-donating NSAID(s) and the porous excipient.

Group XI, claims 1, 39, and 41, drawn to the use of a solid drug delivery composition for treating pain.

Group XII, claims 1, 40, and 42, drawn to the use of a solid drug delivery composition for treating inflammation.

Applicants hereby provisionally elect Group I, claims 1-9 and 19-25, drawn to a solid drug delivery composition comprising NO-donating NSAID(s) absorbed into porous particles, with traverse. Applicants reserve the right to file one or more divisional applications to the non-elected subject matter.

In response to the Election Requirement, Applicants elect species (1), oily and melted forms of NO-donating NSAID(s), with traverse.

This election of Group (1) and species (1) is made **with traverse**. Applicants respectfully submit that the Restriction and Election of Species Requirement is improper. Traversal is also on the grounds that the burden on the Patent Office to consider all of the groups of claims together is less than the burden on Applicants/the public to prosecute/search the applications/patents separately.

Applicants refer to the Manual of Patent Examining Procedure (MPEP) § 803(II), which states:

> "For the purposes of the initial [restriction] requirement, a serious burden on the examiner may be *prima facie* shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02."

Further, as an application subject to PCT Rule 13, Applicants submit that they are entitled to "an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of said product, and an independent claim for a use of the said product" for prosecution in the present application (MPEP § 1850 (III)(1)).

Applicants disagree that each of the twelve (12) groups identified by the Examiner represents a separate invention. For example, Applicants do not believe that Group I (drawn to a solid drug delivery composition comprising NO-donating NSAID(s) absorbed into porous particles) is a separate invention compared to Group II, which directed to the same composition of Group I, with the exception that the composition additionally comprises a surfactant. In addition, Applicants submit that the compositions of Group I and Group II have the same technical effect, providing a solid pharmaceutical

form comprising NO-donating NSAIDs, and therefore the two groups form a single general inventive concept.

As noted on page 11, lines 14-16 of the specification, "[t]he NO-donating NSAIDs may be finely dispersed and absorbed into the porous particles either as the sole drug; as SEDDS [self-emulsifying drug delivery systems]; as a water-in-oil emulsion; as an oil-in-water emulsion; or as a dissolved or melted crystalline drug." Thus, Applicants submit, the SEDDs, which are mixtures of oil(s) and surfactant(s), the water-in-oil emulsions, and the oil-in-water emulsions are all regarded as similar concepts of the NO-donating NSAIDs that can be used in preparing the solid drug delivery compositions of the invention. Therefore, the embodiment relating to the porous particle comprising the NO-donating NSAIDs with the surfactant should be regarded as an alternative realization of the invention, and not a different invention.

As such, reconsideration and withdrawal of the Restriction Requirement and consideration and allowance of all pending claims are respectfully requested.

In view of the Applicants' above elections, Applicants respectfully submit that the Restriction Requirement and the Election of Species Requirement have been satisfied. Applicants submit that claims 1-9 and 19-25 read on the elected invention. Accordingly, Applicants respectfully request examination of claims 1-9 and 19-25 on the merits.

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone

number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this response is not timely filed, the Applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other additional fees which may be required with respect to this response, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. **026220-00054**.

Respectfully submitted,

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